

a. The Controlled Substances Act and the Controlled Substances Analogue Enforcement Act

The Government offers, and Defendants challenge, expert testimony related to alleged violations of the Controlled Substances Act (the “CSA”) and the Controlled Substances Analogue Enforcement Act (the “Analogue Act”). The CSA prohibits a person from dispensing or distributing a controlled substance. *United States v. MacKay*, 715 F.3d 807, 814 (10th Cir. 2013). The Analogue Act provides that a “controlled substance analogue shall, to the extent intended for human consumption, be treated for the purposes of any Federal law as a controlled substance” 21 U.S.C. § 813. A “controlled substance analogue” is defined as a substance:

- (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;
- (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
- (iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

21 U.S.C. § 802(32)(A). The first of the three subparts is read in conjunction with the second two. *McFadden v. United States*, 135 S.Ct. 2298, 2305 n.2 (2015). Thus, a “controlled substance analogue” must have a chemical structure substantially similar to a controlled

substance (“Prong One”) and must have either a substantially similar effect on the central nervous system or be represented or intended to have such an effect (“Prong Two”). *Id.*

b. Expert Testimony Offered by Government

The Government offers the testimony of three experts: Dr. Michael Van Linn, Dr. Gregory Endres, and Dr. Jordan Trecki. Dr. Van Linn has a Ph.D. in Organic Chemistry and is employed as a Drug Science Specialist at the Drug Enforcement Administration (“DEA”). Dr. Van Linn seeks to testify regarding Prong One and opines that seven substances which Defendants are accused of manufacturing and distributing are “substantially similar in chemical structure” to a substance listed on schedule I. [Report of Michael Van Linn, ECF No. 851-1 at 4–17]. Dr. Van Linn arrives at this opinion by reviewing, diagraming, and comparing the chemical structures of the relevant substances. [*Id.*].

Dr. Endres has a Ph.D. in Organic Chemistry and is employed as the Chief Scientific Officer at Pinpoint Testing. Dr. Endres seeks to testify regarding Prong One and opines that seven substances which Defendants are accused of manufacturing and distributing are “substantially similar in chemical structure” to a substance listed on schedule I. [Report of Gregory W. Endres, ECF No. 851-2 at 6–7]. Dr. Endres arrives at this opinion by reviewing, diagramming, and comparing the chemical structures of the relevant substances, comparing their physical characteristics, and comparing the way in which they are metabolized. [*Id.* at 9–46].

Dr. Trecki has a Ph.D. in Pharmacology and is employed as a Pharmacologist at the DEA. Dr. Trecki seeks to testify regarding Prong Two and opines that seven substances which Defendants are accused of manufacturing and distributing have a hallucinogenic effect on the central nervous system that is substantially similar to the hallucinogenic effect of a substance listed on schedule I. [Report of Jordan Trecki, ECF No. 851-3 at 7–32]. Dr. Trecki arrives at

this conclusion by reviewing laboratory and animal studies which test how the relevant substances react within the body and by comparing the reported physiological effects of the relevant substances. [*Id.*]

c. Defendants' Arguments for Exclusion

The Defendants' challenge to the expert testimony offered by the Government is extremely narrow. Defendants request only that the Court exclude "opinions regarding the ultimate issues of whether the substances at issue are substantially similar in chemical structure or pharmacological effect to a controlled substance." [*Daubert* Mot. at 6]. Defendants do not seek to exclude testimony regarding "the similarities and differences in chemical structures and what is known of the pharmacology of the substances involved." [*Id.* at 5–6]. Defendants also make no challenge to the qualifications of the Government's experts or to the accuracy of the diagrams, studies, and reports upon which the Government's experts rely in arriving at their conclusions. Defendants merely ask that the Court prohibit the Government's experts from offering their opinions that the alleged controlled substance analogues are substantially similar in chemical structure or pharmacological effect to controlled substances.

Defendants argue that the Court must exclude this testimony because it is inadmissible under *Daubert*. [*Id.* at 6]. Defendants argue that "the concept of 'substantial similarity' as it relates to molecular structure and pharmacology is not cognizable in science," that "substantially similar is not a term of Chemistry or any other scientific discipline," and that the methodologies used by the Government experts do "not meet even one of the multiple *Daubert* considerations." [Mot. for Pretrial *Daubert* Hearing at 2]. At the hearing, Defendants offered the testimony of four experts who each testified that the phrase "substantially similar," when used in connection with chemical structure or pharmacological effect, does not have an objective scientific meaning.

The Defendants' experts, however, offered their own opinions that the substances at issue are not substantially similar to their scheduled counterparts. On cross examination, the Government's experts each agreed that their final conclusions regarding substantial similarity constitute their own subjective determinations.

II. Legal Standard

Under Federal Rule of Evidence 702, a witness who is qualified as an expert may testify in the form of an opinion or otherwise if (1) the expert's specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue, (2) the testimony is based on sufficient facts or data, (3) the testimony is the product of reliable principles and methods, and (4) the expert has reliably applied the principles and methods to the facts of the case. FED. R. EVID. 702. A party seeking to introduce expert testimony must show (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. *Carlson v. Bioremedi Therapeutic Sys., Inc.*, 822 F.3d 194, 199 (5th Cir. 2016) (citing *Smith v. Goodyear Tire & Rubber Co.*, 495 F.3d 224, 227 (5th Cir. 2007)). The Court, in performing the gatekeeping function identified in *Daubert*, must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Finally, an expert's opinion is not objectionable just because it embraces an ultimate issue. FED. R. EVID. 704.

III. Analysis

The Court finds that the challenged expert testimony is admissible over Defendants' *Daubert* challenge. As an initial matter, the Court finds that the individuals offered by the Government are qualified to testify as experts and that their testimony is relevant. *Daubert*, 509

U.S. at 589. Each individual offered by the government has substantial postgraduate training and employment history in his respective field. *See Carlson*, 882 F.3d at 199 (“Rule 702 does not mandate that an expert be highly qualified in order to testify about a given issue.”). Further, the challenged testimony regarding the similarity of controlled substances and the alleged controlled substance analogues is relevant to facts at issue and will be helpful to the jury. *See* FED. R. EVID. 401; *United States v. Posado*, 57 F.3d 428, 432–33 (5th Cir. 1995) (“Whether evidence assists the trier of fact is essentially a relevance inquiry.”) (citing *Daubert*, 509 U.S. at 591).

Defendants’ *Daubert* Motion argues that the conclusions of the Government’s experts are not science, cannot be tested or verified, and are speculative. [*Daubert* Mot. at 5–7]. At the hearing, the Governments’ experts agreed that their conclusions regarding substantial similarity were their own subjective determinations based on the application of various scientific facts. Therefore, the Court will not permit the Governments’ experts to testify to a degree of scientific certainty regarding the substantial similarity of the substances at issue. *Daubert*, 509 U.S. at 593–94 (identifying factors by which courts may “determin[e] whether a theory or technique is scientific knowledge”).

However, “if a scientist wants to testify to an opinion or conclusion that has not been established to a degree of scientific certainty under *Daubert*, the court may admit the testimony as non-scientific expert testimony under Rule 702 and *Kumho Tire*.” *Restivo v. Hesseman*, 846 F.3d 547, 576–77 (2d Cir. 2017) (“[J]ust as non-scientist experts can testify about their opinions, so too can scientists, when their opinions are based on reliable technical or specialized knowledge, though not scientific fact.”). As the Supreme Court has observed, “[e]xperts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called ‘general truths derived from . . . specialized experience.’” *Kumho Tire Co. v. Carmichael*, 526

U.S. 137, 148 (1999) (citing Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 54 (1901)). “[I]f art appraisers, handwriting experts or economists may express professional opinions that fall short of definitive proof, so may scientists.” *Restivo*, 846 F.3d at 576 (quoting *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 188 (S.D.N.Y. 2005)). However, the Court may admit these opinions only after assessing whether the expert employs “the same level of rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152.

The Court finds that the conclusions of the Government’s experts regarding substantial similarity are the product of rigorous chemical and pharmacological analyses using reliable principles and methods. Dr. Van Linn and Dr. Endres arrive at their conclusions regarding substantial similarity of chemical structure by studying the chemical composition of the substances in question, diagramming this composition, and comparing the composition of the two substances. [Report of Michael Van Linn at 4–17; Report of Gregory W. Endres at 6–7]. Defendants do not argue that Dr. Van Linn or Dr. Endres erred in documenting the chemical structure of the substances at issue or that either witness is unqualified to make reasoned comparisons of the substances’ chemical structures. Diagramming and comparing atomic structure is an established, reliable, and acceptable method for comparing the chemical structure of two substances. *United States v. Bays*, No. 3:13-cr-0357-B, 2014 WL 3764876, at *8 (N.D. Tex. July 31, 2014) (finding Dr. Van Linn’s use of two-dimensional models “a reliable method of comparing the chemical structure of two compounds”). The conclusions of Dr. Van Linn and Dr. Endres are the product of rigorous chemical analyses using reliable principles and methods, reliably applied.

Dr. Trecki arrives at his conclusion regarding substantial similarity of pharmacological effect by reviewing numerous studies for each substance at issue which involve laboratory and animal testing of the substances and detail the substances' physiological effects. [Report of Jordan Trecki at 7–32]. Defendants do not argue that Dr. Trecki misrepresents the results of these studies or that he is unqualified to review and analyze their results. Dr. Trecki's reliance on these studies is a permissible, reliable, and a sufficiently rigorous method by which to examine the similarity of two substances. *Bays*, 2014 WL 3764876, at *13–14 (admitting the testimony of Dr. Trecki over a *Daubert* challenge where his conclusions were based on similar studies). The conclusions of Dr. Trecki are the product of a rigorous pharmacological analysis using reliable principles and methods, reliably applied.

Having made the above determinations, the Court finds that the opinions of the Government's experts regarding substantial similarity are admissible. *Kumho Tire*, 526 U.S. at 152. The Court notes that this decision is in accord with courts across the country which have admitted, or affirmed the admission of, testimony virtually identical to that which Defendants challenge here.¹ The proper method by which Defendants may challenge the conclusions of the Governments' experts is through testimony of their own properly qualified experts² and through

¹ See *United States v. Carlson*, 810 F.3d 544, 553 (8th Cir. 2016); *United States v. Brown*, 415 F.3d 1257, 1262 (11th Cir. 2005); *United States v. Nahmani*, 696 F. App'x 457, 465, 469–74 (11th Cir. 2017); *United States v. Lawton*, 84 F. Supp. 3d 331, 339–40 (D. Vt. 2015); *United States v. Way*, No. 1:14-cr-00101-DAD-BAM, 2018 WL 2229272, at **1–2 (E.D. Cal. May 16, 2018); *United States v. Williams*, No. 13-00236-01/03-CR-W-DGK, 2017 WL 1856081, at *1 (W.D. Mo. Apr. 7, 2017); *United States v. Reulet*, No. 14-400005-DDC, 2015 WL 7776876, at **10–12 (D. Kan. Dec. 2, 2015); *United States v. Hoyt*, No. 2:14CR00001, 2014 WL 5023093, at **1–3 (W.D. Va. Oct. 8, 2014); *United States v. Bays*, No. 3:13-cr-0357-B, 2014 WL 3764876, at **7, 14 (N.D. Tex. July 31, 2014); *United States v. Nasir*, No. 5:12-CR-102-JMH, 2013 WL 5373619, at **1–3 (E.D. Ky. Sept. 25, 2013).

² The Court notes that, while challenging the admissibility of the conclusions of the Government's experts regarding substantial similarity, Defendants offer the testimony of their

cross examination. *Bays*, 2014 WL 3764876, at **7, 14 (“If Defendant wishes to test or otherwise challenge Dr. Trecki’s testimony or the underlying bases of his opinion, he may do so at trial with forceful cross examination and the presentation of contrary evidence.”). The Defendants’ motion seeking to limit the testimony of the Government’s experts under *Daubert* is **DENIED**.

IV. Jury Instruction

The Court is aware that admitting a scientist’s testimony regarding the substantial similarity of the substances at issue may cause the jury to overemphasize the scientific certainty of the testimony. The Court also seeks to ensure that the final determination regarding substantial similarity remains with its proper arbiter, the jury. S. Rep. No. 99-196, at 5 (1985) (“The Committee concurs with the appraisal of the American Chemical Society that the term ‘substantially similar’ chemical structure is meaningful to scientists and *capable of reasoned interpretation by the trier of fact.*” (emphasis added)). Thus, the Court plans to instruct the jury as follows:

I have permitted experts for [the Government or the Government and the Defendants] to offer their opinions, based on their experience in their respective fields, that the substances at issue here are [or are not] substantially similar in chemical structure or pharmacological effect to substances that are listed in schedules I or II of the Controlled Substances Act. These experts’ conclusions regarding substantial similarity do not represent scientific facts, but, rather, are the experts’ own subjective opinions regarding the similarity of the substances at issue formed after their review of certain scientific facts which they deem relevant. Because the statute at issue does not define substantial similarity, it is for you, the jury, to determine whether the Government has proven beyond a reasonable doubt that the substances at issue here are substantially similar in chemical structure or pharmacological effect to those listed in schedules I or II of the Controlled Substances Act. In making this determination, you are to weigh the opinions offered by the experts regarding substantial similarity in the

own experts that the substances at issue are not substantially similar. [*e.g.*, Expert Report of Joseph Ready, ECF No. 776-3 at 256, 260, 265, 269, 274, 278, 283].

same manner in which you weigh all other evidence in this case, giving these opinions as much or as little weight as you deem appropriate.

V. Conclusion

For the reasons articulated in Parts I through III, Defendants' *Daubert* Motion is **DENIED**. In light of this decision, the Court plans to instruct the jury as outlined in Part IV.

SO ORDERED.

August 1, 2018.


BARBARA M. G. LYNN
CHIEF JUDGE